K033191

SOHNIKS ENDOSCOPY, Inc.
930 Blue Gentian Road
Suite 1400
Eagan, MN 55121
(651) 452-4059
Fax (651) 452-4056

MAR - 9 2004

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

This summary of 510(k) safety and effectiveness information is submitted in accordance with the requirements of the Safe Medical Device act of 1990 and 21 CFR 807.92. All data in this document is accurate and complete to the best of Söhniks Endoscopy's knowledge.

Applicant: Söhniks Endoscopy, Inc.
930 Blue Gentian Road
Suite 1400
Eagan, MN 55121
651-452-4059 phone
651-452-4056 fax

Contact: Marc Hoskins

Device ID: Cystoscope

Indication: The intended use for Söhniks Endoscopy, Inc.'s Cystoscopes are for examining, diagnosing, visualizing and to aid in treating the interior problems of the urethra, prostate, bladder, and other urologic problems. This device is used as a visualization device and can be used in conjunction with other instruments to perform various diagnostic and therapeutic procedures.

Device Description: The Söhniks Cystoscopes are reusable manually operated surgical devices that are provided in 0, 30, and 70 degree direction of view. The Cystoscopes are provide non-sterile and must be cleaned and sterilized by the user prior to each use. The components that contact the body are composed of surgical grade stainless steel, which is commonly used in medical devices and has a long history of biocompatibility for human use.

Substantial Equivalence: The Söhniks Cystoscope is substantially equivalent to its predicate devices. The basic design, materials and intended uses are the same and the device is constructed with the same materials as a previouse Söhniks device (#K023783), there are no new issues of safety and effectiveness.

Marc Hoskins
Regulatory Affairs

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR - 9 2004

Mr. Marc Hoskins
Regulatory Affairs
SÖHNIKS Endoscopy, Inc.
930 Blue Gentian Road
Suite 1400
EAGAN MN 55121

Re: K033191
Trade/Device Name: Cystoscope
Regulation Number: 21 CFR §876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: II
Product Code: 78 FAJ
Dated: February 23, 2004
Received: February 23, 2004

Dear Mr. Hoskins:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of the letter:

8xx.1xxx	(301) 594-4591
876.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4616
884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx	(301) 594-4616
892.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4654
Other	(301) 594-4692

Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97) you may obtain. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

K033191

510(k) Number: K033191

Device Name: Cystoscope

Indications for Use:

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DO NOT WRITE BELOW THIS LINE

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓
(Per 21 CFR 801.109)

Nancy C Brogdon
(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K033191

(Optional Format 3-10-98)